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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0263]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Requirements for the Importation of Nonhuman Primates into the United States (formerly Requirements for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States) (OMB Control No. 0920-0263 Exp.6/30/2014)—Revision — National Center Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since May 1990, CDC has monitored the arrival and/or uncrating of certain shipments of non-human primates imported into the United States under a special permit program specific to Cynomolgus, African Green, or Rhesus Monkeys. CDC has monitored compliance with this special permit through the collection of information focused on determining whether or not importers conduct adequate disease control practices. Importers were required to renew their special permit every 180 days.

In February 2013, CDC promulgated two regulations pertaining to the importation of nonhuman primates. The first rule, Requirements for Importers of Nonhuman Primates (2/15/2013, Vol. 78, No. 32 /p. 11522) consolidates into 42 CFR 71.53 the requirements previously found in 42 CFR part 71.53 with those found in the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States. It also extended the time period for registration/permit renewal from 180 days to 2 years. The Special Permit has been withdrawn. The requirements found therein are now incorporated into the revised final rule for 42 CFR 71.53. The second rule, Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples (2/12/2013, Vol.78, No. 29, p.9828), outlines a process by which

importers can send liver tissues to CDC from primates that die during importation from reasons other than trauma. CDC performs these tests due to the absence of a private sector option.

CDC feels these regulatory changes balance the public health risks posed by the importation of nonhuman primates with the burden imposed on regulating their importation.

These rule changes have prompted CDC to modify how it administers the information collected from the public in the enforcement of nonhuman primate regulations. CDC is requesting the following changes:

1. CDC requests that this information collection request be re-named "Requirements for the Importation of Nonhuman Primates into the United States" to more accurately reflect the type of information that is requested from respondents.
2. To streamline administration of this information collection request, CDC requests that CDC form 75.10A Application for Registration as an Importer of Nonhuman Primates and the Recordkeeping requirement currently approved under OMB Control Number 0920-0134 Foreign Quarantine Regulations, be moved and included in this revision to OMB Control Number 0920-0263. This action places all nonhuman primate information collection requirements and requests into one information collection request administered by CDC.

3. CDC is renaming the different portions of the information collected in this information collection to more accurately list the types of forms and documentation CDC collects from importers of nonhuman primates. Therefore, the former information categories of Businesses (limited permit), Businesses (extended permit), and Organizations (extended permit) are being renamed and reorganized. The information contained in these categories will now be accounted for in the Documentation sections of the burden table. This categorization will more accurately reflect CDC's interaction with the importers.
4. CDC also requests additional burden hours to account for notification to CDC from importers of shipment arrivals and requests for release from quarantine.
5. CDC further requests the addition of the Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials, which will be used to collect all of the necessary information from nonhuman primate importers to test nonhuman primate liver samples for filovirus and communicate the results of this test. This action adds approximately 50 hours of burden to this information collection request.

This information collection involves minimal personally identifiable information and should have limited impact on an

individual's privacy. There are no costs to respondents other than their time.

The total burden requested for this information collection is 146.

Estimated Annualized Burden Hours

Type of Respondent	Form Name/CFR Reference	# of Respondents	# of Responses per Respondent	Average Burden per Response (in hours)
Nonhuman Primate Importer	71.53 (g) New Importer Registration - Nonhuman Primates	1	1	10/60
Nonhuman Primate Importer	71.53 (g) Importer Re-Registration - Nonhuman Primates	12	1	10/60
Nonhuman Primate Importer	71.53 (h) Documentation (no form) (New Importer)	1	1	10
Nonhuman Primate Importer	71.53 (h) Documentation (no form) (Registered Importer)	12	1	30/60
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53 (n) (no form)	25	6	15/60
Nonhuman Primate Importer	Quarantine release 71.53 (l) (No form)	25	6	15/60
Nonhuman Primate Importer	71.53 (v) Form: Filovirus	10	15	20/60

	Diagnostic Specimen Submission Form for Non- human Primate Materials			
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